Message

From: Francesca ZOETE MAGLIA [Francesca.ZOETE.MAGLIA@firmenich.com]

Sent: 9/20/2018 2:14:59 PM

To: Miller, Monica [miller.monica@epa.gov]; Richard E. Engler, Ph.D. [rengler@lawbc.com]

CC: Hilton, Geraldine [Hilton.Geraldine@epa.gov]; Bauer, Jeff [Bauer.Jeff@epa.gov]; John CAREY

[John.CAREY@firmenich.com]

Subject: Re: Request for Suspension and Administrative Needs + request of meeting

Hi Monica

Sylvia is our environmental expert which is also working on risk assessment.

She is interested on all the PMNs at stake: 14, 26 and 70.

May I suggest I call you directly to organize this meeting?

I find calls better than emails.

Enjoy your day, Francesca



Global Regulatory Services

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NEXT OoO: 24SEP-05OCT18

+41 22 780 31 06

From: Miller, Monica <miller.monica@epa.gov>

Sent: 20 September 2018 16:01

To: Francesca ZOETE MAGLIA; Richard E. Engler, Ph.D.

Cc: Hilton, Geraldine; Bauer, Jeff; John CAREY

Subject: RE: Request for Suspension and Administrative Needs + request of meeting

Francesca,

I'd like to make sure the right person from the Risk Assessment Division is available.

What is Dr. Sylvia GIMENO's area of expertise and may I have only the last two digits of the PMN of interest?

Thank you, Monica Miller

Environmental Protection Specialist

New Chemicals Management Branch

US EPA, OPPT

Phone: 202-564-6473 Fax: 202-564-9490

From: Francesca ZOETE MAGLIA [mailto:Francesca.ZOETE.MAGLIA@firmenich.com]

Sent: Thursday, September 20, 2018 9:39 AM

To: Miller, Monica <miller.monica@epa.gov>; Richard E. Engler, Ph.D. <rengler@lawbc.com>

Cc: Hilton, Geraldine <Hilton.Geraldine@epa.gov>; Bauer, Jeff <Bauer.Jeff@epa.gov>; John CAREY

<John.CAREY@firmenich.com>

Subject: Re: Request for Suspension and Administrative Needs + request of meeting

Hello Monica

we are fine for a meeting on Oct 2nd at 2pm.

At this stage, the participants are the following:

M John CAREY

M Richard ENGLER

Ms Francesca ZOETE

Dr Sylvia GIMENO by conference call

Enjoy your day, Francesca



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NEXT OoO: 24SEP-05OCT18

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From: Miller, Monica <miller.monica@epa.gov>

Sent: 19 September 2018 21:42

To: Francesca ZOETE MAGLIA; Richard E. Engler, Ph.D.

Cc: Hilton, Geraldine; Bauer, Jeff

Subject: RE: Request for Suspension and Administrative Needs + request of meeting

Francesca & Rich,

I have tentatively set the meeting up for 2pm on October 2nd.

Please let me know if this does not work and if there are others beside Rich and yourself attending.

Thank you,

Monica Miller

Environmental Protection Specialist New Chemicals Management Branch

US EPA, OPPT

Phone: 202-564-6473 Fax: 202-564-9490

From: Francesca ZOETE MAGLIA [mailto:Francesca.ZOETE.MAGLIA@firmenich.com]

Sent: Wednesday, September 19, 2018 12:36 PM

To: Miller, Monica <miller.monica@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>; Richard E. Engler, Ph.D.

<rengler@lawbc.com>

Cc: Hilton, Geraldine < <u>Hilton.Geraldine@epa.gov</u>>; Bauer, Jeff < <u>Bauer.Jeff@epa.gov</u>> **Subject:** RE: Request for Suspension and Administrative Needs + request of meeting

Hello Monica

Thanks for the follow up.

The scope is to follow up the 08FEB18 meeting with EPA and assess any open points on both sides.

On Firmenich side, please find what we suggest as agenda:

- 1. Agreement found after the 08FEB18 meeting
 - a. No SNUR on water release
- 2. Which is the current status of the PMNs
 - PMN 16-0314: check if the last information provided is enough to address EPA initial concerns and obtain TSCA listing

- PMN 16-0326: check if the last information provided is enough to address EPA initial concerns and obtain TSCA listing
 - i. Jeff mentioned to resubmit the PMN; is it possible to explain why?
- PMN 16-0470: check if the last information provided is enough to address EPA initial concerns and obtain TSCA listing

Jeff

We would be most grateful to set up a different discussion with David TOBIAS to evaluate the fate of P15-0633: as this PMN is at a different step of assessment than the other three, we suggest having a different discussion where our photodegradation and environmental experts could participate, to follow up the call we had this summer.

I remain available for further detail for the meeting organization.

FYI: I will be in the US starting this Monday; therefore reachable in a convenient way for EPA and for a longest amount of time.

ENJOY YOUR DAY, FRANCESCA



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NEXT OoO: 24SEP-05OCT18

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From: Miller, Monica [mailto:miller.monica@epa.gov]

Sent: mardi 18 septembre 2018 18:46

To: Francesca ZOETE MAGLIA; Schweer, Greg; Richard E. Engler, Ph.D.

Cc: Hilton, Geraldine; Bauer, Jeff

Subject: RE: Request for Suspension and Administrative Needs + request of meeting

Hi Francesca,

Thank you for the notice of the CDX submission, I did review it. I will be happy to set up a meeting based on the schedule you provided. Please provide an agenda.

Monica Miller

Environmental Protection Specialist New Chemicals Management Branch

US EPA, OPPT

Phone: 202-564-6473 Fax: 202-564-9490

From: Francesca ZOETE MAGLIA [mailto:Francesca.ZOETE.MAGLIA@firmenich.com]

Sent: Tuesday, September 18, 2018 9:24 AM

To: Miller, Monica <<u>miller.monica@epa.gov</u>>; Schweer, Greg <<u>Schweer.Greg@epa.gov</u>>; Richard E. Engler, Ph.D. <rengler@lawbc.com>

Cc: Hilton, Geraldine < Hilton. Geraldine@epa.gov >; Bauer, Jeff < Bauer. Jeff@epa.gov > Subject: RE: Request for Suspension and Administrative Needs + request of meeting

Hello Monica

I have just submitted via CDX the request to add myself as support for P16-470.

As already mentioned, I am travelling to the US shortly. My intention is to have the chance to review the technical details currently under EPA consideration for P16-314, 326 and 470 with EPA relevant staff.

Would you mind evaluating this technical discussion to sort out these three cases?

I will be in the US from Sep 24th to Oct 5th. Some days are already blocked: Sep 25-26 and Oct 3-4th. The other days are open.

I remain available for any further information.

ENJOY YOUR DAY, FRANCESCA



NEXT OoO: 24SEP-05OCT18

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From: Miller, Monica [mailto:miller.monica@epa.gov]

Sent: mercredi 12 septembre 2018 16:13

To: Francesca ZOETE MAGLIA; rengler@lawbc.com; Kerry BLISSETT

Cc: Hilton, Geraldine; Bauer, Jeff

Subject: RE: Request for Suspension and Administrative Needs

Francesca,

I understand you are the Primary Authorized Official to submit information thru CDX but you are not listed in the PMN or any amendment or support document as the Person submitting the Notice or an authorized technical contact or other contact for the PMN. I need documentation submitted thru CDX in order to have discussions because there is information in the PMN marked CBI. I know this is frustrating, please see the Commun S dated 10/13/2016 in CDX giving permission to discuss information with Rich Engler and Sheryl Dolan.

Thank you, Monica Miller Environmental Protection Specialist New Chemicals Management Branch US EPA, OPPT

Phone: 202-564-6473 Fax: 202-564-9490

From: Francesca ZOETE MAGLIA [mailto:Francesca.ZOETE.MAGLIA@firmenich.com]

Sent: Wednesday, September 12, 2018 9:49 AM

To: Miller, Monica <miller.monica@epa.gov>; rengler@lawbc.com

Cc: Hilton, Geraldine < Hilton. Geraldine@epa.gov>; Bauer, Jeff < Bauer. Jeff@epa.gov>

Subject: RE: Request for Suspension and Administrative Needs

Hello Monica

As my role within CDX is Primary Authorized Official, I should be able to discuss the current PMNs with EPA Program manager.

As a proof, I am sharing a print screen of CDX:

If this is not the appropriate way to address your request, I will then submit an authorization via CDX.

Concerning your request of suspension, I will submit it today, once the AO role is formally recognized. ENJOY YOUR DAY, FRANCESCA



L&C, GRS SENIOR MANAGER PE&I REGISTRATION

NEXT OoO: 17SEP18 +41 22 780 31 06

From: Miller, Monica [mailto:miller.monica@epa.gov]

Sent: mardi 11 septembre 2018 18:33

To: Francesca ZOETE MAGLIA; rengler@lawbc.com

Cc: Hilton, Geraldine; Bauer, Jeff

Subject: Request for Suspension and Administrative Needs

Importance: High

Francesca,

I did receive your voicemail yesterday. I am still waiting on the finalization of the review of one support document submitted. In an earlier email there was reference to perhaps another document to be submitted. Please verify only one support document has been submitted.

At the moment I have no authorization in CDX from Firmenich authorizing me to discus PMN matters with you. You are not listed as contact in any document submitted via CDX. You must be authorized before I can discuss any CBI with you, or process suspensions of the review period.

Rich,

Because Francesca is not authorized on my end, please provide a request for suspension on behalf of Firmenich. The review period will end on Friday 9/14/2018. As you know I can process up to 2 -15 day suspensions by replying to this email with the request. If a longer suspension is desired please submit the request through CDX.

I am still waiting on the finalization of the review of one support document submitted. In an earlier email there was reference to perhaps another document to be submitted. Please verify only one support document has been submitted

Thank you,
Monica Miller
Environmental Protection Specialist
New Chemicals Management Branch
US EPA, OPPT

Phone: 202-564-6473 Fax: 202-564-9490

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